

WHAT IS CLAIMED:

Claim 1. A method for purifying cancer-specific (csPCNA) comprising the steps of:

- (A) obtaining a tissue or body fluid sample comprising csPCNA;
- (B) contacting said sample with a peptide comprising the amino acid sequence

LeuLysGlnLeuAspAlaGlnGlnThrGlnLeuArg
IleAspSerPhePheArgLeuAlaGlnGlnGluLys
GluAspAlaLysArg (SEQ ID NO:1),
wherein said peptide is immobilized
on a solid support and binds to said
csPCNA to form a peptide-csPCNA
complex; and

- (C) isolating csPCNA from said peptide-csPCNA complex so as to purify said csPCNA.

Claim 2. The method of Claim 1, wherein prior to step (B) the thus obtained tissue or body fluid sample of step (A) is subjected to a process comprising:

- (1) homogenizing cells constituting said tissue or body fluid to obtain a homogenate (H);
- (2) separating said H into a nuclear pellet fraction (NP) and a cytosolic fraction (S1);
- (3) extracting nuclei from said NP to obtain a nuclear extract (NE);
- (4) subjecting said S1 to centrifugation to obtain a

post-mitochondrial cytosolic supernatant (S2);

(5) subjecting said S2 to centrifugation to obtain a post-mitochondrial/post-microsomal cytosolic supernatant (S3);

(6) combining said NE and said S3 to form an NE/S3 fraction, applying the resulting NE/S3 fraction to a weak anion exchange matrix column and collecting the flow through (PCFT);

(7) applying the resulting PCFT to a hydrophobic chromatography matrix column, eluting the column with buffer comprising ethylene glycol and collecting the eluant (PSE);

(8) dialyzing out ethylene glycol present in the PSE to obtain a dialyzate; and

(9) applying the resulting dialyzate to a strong anion exchange matrix column, eluting with a dialyzate buffer comprising a salt gradient, and collecting and pooling PCNA-containing fractions to obtain said sample.

Claim 3. The method of Claim 1 or 2, wherein said tissue or body fluid sample of step (A) further comprises native PCNA (nPCNA), said nPCNA does not bind to said peptide in step (B), whereas said csPCNA binds to said peptide in step (B) to form a peptide-csPCNA complex and in step (C) isolating csPNA is effected using an elution buffer whereby csPNA is eluted from said csPNA-complex.

Claim 4. An immunoassay for detecting csPCNA comprising:

- (1) contacting a test sample with a peptide comprising the amino acid sequence LeuLysGlnLeuAspAlaGlnGlnThrGlnLeuArgIle AspSerPhePheArgLeuAlaGlnGlnGluLysGluAsp AlaLysArg (SEQ ID NO:1), which has been immobilized on a solid support so as to bind csPCNA to said peptide to form a peptide-csPCNA complex; and
- (2) contacting said peptide-csPCNA complex with an anti-PCNA antibody and detecting binding of said antibody to said complex.

Claim 5. The immunoassay of Claim 4, wherein said assay is an ELISA and said antibody is labeled with a detectable enzyme.

Claim 6. The immunoassay of Claim 5, wherein said enzyme is horse radish peroxidase.

Claim 7. The immunoassay of Claim 5, wherein said peptide is a fusion protein comprising said peptide and Glutathione-S-Transferase.

Claim 8. The immunoassay of Claim 7, wherein said fusion protein is biotinylated and immunobilization on said solid support via streptavidin-coated on said solid support.